# UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

MONSANTO COMPANY and	)	
MONSANTO TECHNOLOGY LLC,	)	
	)	
Plaintiffs,	)	
	)	
VS.	)	
	)	
E.I. DUPONT DE NEMOURS AND	)	Case No. 4:09-cv-686 ERW
COMPANY and PIONEER HI-BRED	)	
INTERNATIONAL,	)	
INC.,	)	
	)	
Defendants.	)	

MONSANTO'S RESPONSES TO DEFENDANTS' STATEMENT OF
UNCONTROVERTED MATERIAL FACTS AND STATEMENT OF ADDITIONAL
MATERIAL FACTS

Plaintiffs Monsanto Company and Monsanto Technology LLC ("Monsanto")
respectfully submit the following Responses to Defendants' Statement of Uncontroverted
Material Facts and Statement of Additional Material Facts in support of Monsanto's Opposition
to Defendants' Motion for Summary Judgment of Invalidity for Broadened Reissue Claims.

## RESPONSES TO DEFENDANTS PURPORTED FACTS

# **Defendants' Headings And Legal Conclusions:**

Defendants' purported Statement of Facts contains headings that are either unsupported allegations or legal conclusions to which Monsanto need not respond. To the extent any response is required, Monsanto denies Defendants' characterizations and legal conclusions and respectfully refers the Court to Monsanto's brief in opposition to the instant motion, which is incorporated herein by reference. Each of Defendants' numbered Purported Facts is addressed below.

## **Defendants' Purported Fact No.1**:

On May 4, 2009, Monsanto filed a Complaint in this matter, alleging, *inter alia*, that Defendants have infringed claims of U.S. Patent No. RE39,247 ("the '247 Reissue Patent") and have induced third parties to infringe claims of the '247 Reissue Patent.

#### **Monsanto Response:**

UNCONTROVERTED that on May 4, 2009, Monsanto filed a Complaint in this matter, alleging, *inter alia*, that Defendants have infringed both directly and indirectly claims of U.S. Patent No. RE39,247 ("the '247 Reissue Patent").

#### **Defendants' Purported Fact No. 2**:

In their Amended Answer and Counterclaims, Counterclaims IX and X filed on July 10, 2009, Defendants allege that Monsanto's '247 Reissue Patent is invalid for, *inter alia*, failure to

"satisfy one or more of the requirements for patentability specified in 35 U.S.C. §§ 101, et seq., and/or non-statutorily and judicially invoked doctrines of invalidity."

# **Monsanto Response:**

UNCONTROVERTED that Defendants so alleged. Defendants' pleading does not specifically plead that the '247 Reissue Patent or any of its claims are invalid for broadening reissue.

## **Defendants' Purported Fact No. 3**:

On July 21, 2009, Monsanto answered Defendants' Amended Counterclaims.

# **Monsanto Response:**

UNCONTROVERTED that on July 21, 2009, Monsanto answered Defendants' Amended Counterclaims.

## **Defendants' Purported Fact No. 4**:

On May 27, 1997, U.S. Patent No. 5,633,435 (the "'435 Patent") was granted to Gerald F. Barry et al., entitled "Glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthases."

#### **Monsanto Response:**

UNCONTROVERTED that the '435 Patent was so granted and so titled.

## **Defendants' Purported Fact No. 5**:

The '435 Patent consists of five independent claims: Claim 1, 4, 15, 32, 86.

## **Monsanto Response:**

UNCONTROVERTED that the '435 Patent contains five independent claims: Claim 1, 4, 15, 32, 86.

## **Defendants' Purported Fact 5.1**:

- Claim 1 is directed to: "An isolated DNA molecule which encodes an EPSPS enzyme having the sequence of SEQ ID NO: 3."
- Claim 4 is directed to: "A recombinant, double-stranded DNA molecule comprising in sequence:
  a) a promoter which functions in plant cells to cause the production of an RNA sequence;
  - b) a structural DNA sequence that causes the production of an RNA sequence which encodes a EPSPS enzyme having the sequence domains:
  - -R-X1-H-X2-E-(SEQ ID NO:37), in which X1 is G, S, T, C, Y, N, Q, D or E; X2 is S or T; and
  - -G-D-K-X3-(SEQ ID NO:38), in which X3 is S or T; and
  - -S-A-Q-X4-K-(SEQ ID NO:39), in which X4 is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y or V; and
  - -N-X5-T-R(SEQ ID NO:40), in which X5 is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y or V; and
  - c) a 3' non-translated region which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence;
  - where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the encoded EPSPS enzyme to enhance the glyphosate tolerance of a plant cell transformed with the DNA molecule."
  - Claim 15 is directed to: "A method of producing genetically transformed plants which are tolerant towards glyphosate herbicide, comprising the steps of:
    - a) inserting into the genome of a plant cell a recombinant double-stranded DNA molecule comprising:
    - i) a promoter which functions in plant cells to cause the production of an RNA sequence;
    - ii) a structural DNA sequence that causes the production of an RNA sequence which encodes a EPSPS enzyme having the sequence domains:
    - -R-X1-H-X2-E-(SEQ ID NO:37), in which X1 is G, S, T, C, Y, N, Q, D or E; X2 is S or T; and
    - -G-D-K-X3-(SEQ ID NO:38), in which X3 is S or T; and
    - -S-A-Q-X4-K-(SEQ ID NO:39), in which X4 is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y or V; and
    - -N-X5-T-R(SEQ ID NO:40), in which X5 is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y or V; and
    - iii) a 3' non-translated region which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence;

- where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the polypeptide to enhance the glyphosate tolerance of a plant cell transformed with the DNA molecule;
- b) obtaining a transformed plant cell; and
- c) regenerating from the transformed plant cell a genetically transformed plant which has increased tolerance to glyphosate herbicide."
- Claim 32 is directed to: "A method for selectively controlling weeds in a field containing a crop having planted crop seeds or plants comprising the steps of:
  - a) planting the crop seeds or plants which are glyphosate-tolerant as a result of a recombinant double-stranded DNA molecule being inserted into the crop seed or plant, the DNA molecule having:
  - i) a promoter which functions in plant cells to cause the production of an RNA sequence.
  - ii) a structural DNA sequence that causes the production of an RNA sequence which encodes an EPSPS enzyme having the sequence domains:
  - -R-X1-H-X2-E-(SEQ ID NO:37), in which X1 is G, S, T, C, Y, N, Q, D or E; X2 is S or T; and
  - -G-D-K-X3-(SEQ ID NO:38), in which X3 is S or T; and
  - -S-A-Q-X4-K-(SEQ ID NO:39), in which X4 is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y or V; and
  - -N-X5-T-R(SEQ ID NO:40), in which X5 is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y or V; and
  - iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence;
  - where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the EPSPS enzyme to enhance the glyphosate tolerance of the crop plant transformed with the DNA molecule; and
  - b) applying to the crop and weeds in the field a sufficient amount of glyphosate herbicide to control the weeds without significantly affecting the crop.
- Claim 86 is directed to: "A transgenic soybean plant which contains a heterologous gene which encodes an EPSPS enzyme having a Km for phosphoenolpyruvate (PEP) between 1 and 150 µM and a Ki(glyphosate)/Km(PEP) ratio between about 2 and 500, said plant exhibiting tolerance to N-phoshonomethylglycine herbicide at a rate of 1lb/acre without significant yield reduction due to herbicide application."

## **Monsanto Response:**

UNCONTROVERTED that the claims are quoted from the '247 Patent.

# **Defendants' Purported Fact No. 6**:

Upon receiving the '435 Patent grant, Monsanto sued numerous farmers for infringement of the '435 Patent. See, e.g., Monsanto Co. v. Dawson, No. 4:98CV02004 (E.D. Mo.); Monsanto Co. v. Mayfield, No. 4:99CV00538 (E.D. Mo.); Monsanto Co. v. Stratemeyer, No. 4:99CV04197 (S.D. Ill.); Monsanto Co. v. McFarling, No. 4:00CV00084 (E.D. Mo.); Monsanto Co. v. Trantham, No. 2:00CV02656 (W.D. Tenn.); Monsanto Co. v. Swann, No. 4:00CV01481 (E.D. Mo.); Monsanto Co. v. Ethridge, No. 4:00CV01592 (E.D. Mo.); Monsanto Co. v. Ralph, No. 4:00CV00135 (E.D. Mo.); Monsanto Co. v. Hendrix, No. 4:01CV00523 (E.D. Mo.); Monsanto Co. v. Kelly, No. 4:01CV01484 (E.D. Mo.); Monsanto Co. v. White, No. 4:00CV01761 (E.D. Mo.); Monsanto Co. v. Jones, No. 3:00CV00188 (N.D. Miss.); Monsanto Co. v. Adams, No. 3:00CV00185 (N.D. Miss.); Monsanto Co. v. Nelson, No. 4:00CV01636 (E.D. Mo.).

## **Monsanto Response:**

UNCONTROVERTED that Monsanto has filed suit against certain parties who have infringed Monsanto's patent rights.

## **Defendants' Purported Fact No. 7**:

On September 7, 2000, Monsanto filed suit against farmer Mitchell Scruggs, *Monsanto Co. v. Scruggs*, No. 3:00-CV-00161 (N.D. Miss.), asserting '435 Patent genus claims.

## **Monsanto Response:**

UNCONTROVERTED that Monsanto filed suit against Mitchell Scruggs and that Monsanto initially alleged infringement of the '435 Patent in the *Scruggs* litigation.

## **Defendants' Purported Fact No. 7.1**:

Scruggs repeatedly asserted that the '435 Patent was invalid in various pleadings.

#### **Monsanto Response:**

UNCONTROVERTED that Defendant Scruggs alleged the invalidity of the '435 Patent.

## **Defendants' Purported Fact No. 8**:

On July 16, 2002, Monsanto moved to amend its Complaint against Scruggs and withdraw its Purported Fact of infringement based on the '435 Patent.

## **Monsanto Response:**

UNCONTROVERTED that Monsanto amended its complaint so that it was no longer asserting the '435 Patent.

## **Defendants' Purported Fact No. 9**:

On August 11, 2003, Scruggs filed a motion for summary judgment asserting the '435 Patent was invalid as a matter of law.

## **Monsanto Response:**

UNCONTROVERTED that on August 11, 2003, Defendant Scruggs filed a motion for summary judgment asserting the '435 Patent was invalid.

## **Defendants' Purported Fact No. 10**:

On July 18, 2003, Monsanto filed Reissue Patent Application Serial No. 10/622,201, which issued on August 22, 2006, as the '247 Reissue Patent.

## **Monsanto Response:**

UNCONTROVERTED that on July 18, 2003, Monsanto filed Reissue Patent Application Serial No. 10/622,201, and that Reissue Patent Application Serial No. issued on August 22, 2006, as the '247 Reissue Patent.

## **Defendants' Purported Fact No. 10.1**:

The Statement of the Invention, in the specification of the '247 Reissue Patent, states: "The promoter region contains a sequence of bases that signals RNA polymerase to associate with the DNA, and to initiate the transcription into mRNA using one of the DNA strands as a template to make a corresponding complementary strand of RNA."

## **Monsanto Response:**

UNCONTROVERTED that Statement of Fact 10.1 is a quote of a portion of the specification of the '247 Patent.

## **Defendants' Purported Fact No. 10.2**:

The Statement of the Invention further states: "The 3' non-translated region of the chimeric plant gene contains a polyadenylation signal which functions in plants to cause the addition of polyadenylate nucleotides to the 3' end of the viral RNA."

## **Monsanto Response:**

UNCONTROVERTED that Statement of Fact 10.2 is a quote of a portion of the specification of the '247 Patent.

## **Defendants' Purported Fact No. 11**:

Monsanto added claims 102 and 115-127 (hereinafter the "Promoterless Claims") in the '247 Reissue Patent that were not present in the '435 Patent. These Promoterless Claims are broader than each and every claim of the '435 Patent. Each of these claims is directed, in part, to a DNA sequence encoding an EPSPS enzyme having the sequence of SEQ ID NO:70.

- Claim 102 is directed to: "An isolated DNA molecule that encodes a 5enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme having the sequence of SEQ ID NO: 70."
- Claim 115 is directed to: "A glyphosate-tolerant plant cell comprising a DNA sequence encoding an EPSPS enzyme having the sequence of SEQ ID NO: 70."
- Claim 116 is directed to: "A glyphosate-tolerant plant comprising a DNA sequence encoding an EPSPS enzyme having the sequence of SEQ ID NO: 70."
- Claim 117 is directed to: "The plant of claim 116, wherein the plant is corn, wheat, rice, barley, soybean, cotton, sugarbeet, oilseed rape, canola, flax, sunflower, potato, tobacco, tomato, alfalfa, poplar, pine, eucalyptus, apple, lettuce, peas, lentils, grape or turf grasses."
- Claim 118 is directed to: "The plant of claim 117, wherein the plant is corn."
- Claim 119 is directed to: "The plant of claim 117, wherein the plant is soybean."
- Claim 120 is directed to: "The plant of claim 117, wherein the plant is canola."
- Claim 121 is directed to: "The plant of claim 117, wherein the plant is cotton."
- Claim 122 is directed to: "A seed of the plant of claim 116, wherein the seed comprises the DNA sequence encoding an EPSPS enzyme having the sequence of SEQ ID NO: 70."
- Claim 123 is directed to: "The seed of claim 122, wherein the seed is corn, wheat, rice, barley, soybean, cotton, sugarbeet, oilseed rape, canola, flax, sunflower, potato, tobacco, tomato, alfalfa, poplar, pine, eucalyptus, apple, lettuce, peas, lentils, grape or turf grass seed."
- Claim 124 is directed to: "The seed of claim 123, wherein the seed is corn seed."
- Claim 125 is directed to: "The seed of claim 123, wherein the seed is soybean seed."
- Claim 126 is directed to: "The seed of claim 123, wherein the seed is canola seed."

Claim 127 is directed to: "The seed of claim 123, wherein the seed is cotton seed."

## **Monsanto Response:**

UNCONTROVERTED that Claims 102 and 115-127 were added during reissue.

UNCONTROVERTED that each of these claims contains the quoted language.

The remaining purported "facts" and legal conclusions of paragraph 11 are CONTROVERTED.

The challenged claims of the '247 Patent asserted by Monsanto are not "promoterless." As Defendants admit in their opening claim construction brief, the DNA encoding SEQ ID NO:70 must be *functional*. Although Monsanto's claim constructions differ in certain respects from those of Defendants, both require such functionality. Defendants' position is that the "glyphosate tolerant plant" and "glyphosate tolerant plant cell" of the claims require that the glyphosate tolerance of the claimed plants or plant cells must be "due to the production of a glyphosate-tolerant EPSPS enzyme which has the exact sequence of' SEQ ID NO:70. (Dkt. No. 243 at 40). *See also* Monsanto's construction of the phrase "glyphosate tolerant" plant or plant cells, which requires that the glyphosate tolerance be due at least to a functional DNA molecule *encoding* SEQ ID NO:70 that has been inserted into the plant's genome. (Dkt. No. 259 at 33, 37).

To confer glyphosate tolerance, the inserted DNA encoding SEQ ID NO:70 ultimately must cause the production of EPSPS enzymes. (Dellaporta Decl.,  $\P 9)^1$ . A functional gene is required for the EPSPS enzymes to be produced, and hence, for glyphosate tolerance to be achieved in the plant or plant cell. (*Id.*,  $\P 10$ ). Scientifically, it would be impossible to impart glyphosate tolerance to a plant or plant cell using a structural DNA sequence encoding SEQ ID

<sup>&</sup>lt;sup>1</sup> All references to "Dellaporta Decl." throughout this document refer to the Declaration of Dr. Stephen Dellaporta in Support of Monsanto's Opposition to Defendants' Motion for Summary Judgment of Invalidity, dated July 12, 2010, filed herewith.

NO:70 if that structural DNA sequence lacked a promoter capable of functioning inside a plant cell to cause transcription. (*Id.*, ¶¶ 9-11). Moreover, in order to function in plant cells, the promoter must be "heterologous with respect to the structural DNA sequence." (*Id.*, ¶¶ 15-19). Likewise, it would be impossible for DNA encoding an EPSPS enzyme having SEQ ID NO:70 to confer glyphosate tolerance in a plant or plant cell, unless that DNA had a 3′ non-translated region ("3′ NTR") capable of signaling polyadenylation of the RNA transcript. (*Id.*, ¶¶ 20-24). Consequently, there is no conceivable plant cell, plant, or seed that is glyphosate tolerant due to structural DNA encoding an EPSPS enzyme containing SEQ ID NO:70, which lacks a heterologous promoter and 3′ NTR. (*Id.*, ¶¶ 12, 19, 24).

Defendants' statement that the challenged claims of the '247 Patent are broader than any claim in the '435 Patent is a conclusion of law, not a statement of fact, and thus Monsanto need not respond here. To the extent any response is required, the challenged claims of the '247 Patent added an element – glyphosate tolerance – which can only be conferred by a functional DNA construct which inherently includes all the elements of Claim 4 of the '435 Patent, as demonstrated by the evidence cited above. In addition, the challenged claims are directed to a specific DNA sequence, and are thus *narrower* than Claim 4 of the '435 Patent. (Ex. 5, '247 File History, Sept. 12, 2005, Examiner's Amend. at 5); Dellaporta Decl., ¶¶ 25-27

# **Defendants' Purported Fact No. 12**:

As shown in the '247 Reissue Patent, enzymes having the sequence of SEQ ID NO:3 and SEQ ID NO:70 are different, as SEQ ID NO:70 requires an enzyme starting with three residues Met-Leu-His, whereas SEQ ID NO:3 requires Met-Ser-His. Therefore, embodiments covered by the '247 Reissue Patent claim 102, would not necessarily infringe original claim 1.

## **Monsanto Response:**

CONTROVERTED that enzymes having the sequence of SEQ ID NO:3 and SEQ ID NO:70 are "different." There is no functional difference between SEQ ID NO:3 and SEQ ID NO:70. (Ex. 10, '435 Patent, col. 28, Il 45-57; '247 Patent, col. 29, Il. 14-24).

Defendants' statement that embodiments covered by claim 102 of the '247 Patent would not necessarily infringe claim 1 of the '435 Patent is a conclusion of law, not a statement of fact, that Monsanto need not address here. To the extent that any response is required, embodiments that infringe claim 102 of the '247 Patent would infringe claim 1 of the '435 patent by, at least, the doctrine of equivalents.

# **Defendants' Purported Fact No. 13**:

The Promoterless claims of the '247 Reissue Patent lack limitations present in original claims 4, 15 and 32 of the '435 Patent. The Promoterless Claims do not require a "recombinant" "heterologous" "function[al]" "promoter" or a "recombinant" "function[al]" "3' non-translated region" while original claims 4, 15, and 32 of the '435 Patent each recite these limitations.

## **Monsanto Response:**

The purported "facts" and legal conclusions of paragraph 13 are CONTROVERTED.

The challenged claims of the '247 Patent asserted by Monsanto are not "promoterless," and inherently include all the elements of Claim 4 of the '435 Patent. They require a "heterologous" "function[al]" "promoter" and a "function[al]" "3' non-translated region." *See* Monsanto's Response to Defendants' Purported Fact No. 11, above, which is incorporated herein.

The word "recombinant" appears in the preamble of claim 4 of the '435 Patent, and to the extend it is a limitation at all, it is not used, as Defendants' appear to suggest, to modify either "promoter" or "3' non-translated region." (Ex. 10, claim 4). Rather, "recombinant" modifies "double-stranded DNA molecule" in the preamble. "Recombinant" simply means "relating to or containing genetically engineered DNA." (*See* Merriam-Webster OnLine Dictionary at

http://merriam-webster.com/dictionary/recombinant). Both the DNA of claim 4 and the DNA of the challenged reissue claims are genetically engineered.

## **Defendants' Purported Fact No. 14**:

The Promoterless claims of the '247 Reissue Patent lack limitations present in original claim 86 of the '435 Patent. The Promoterless Claims do not require a "transgenic soybean plant" "which encodes an EPSPS enzyme having a Km for phosphoenolpyruvate (PEP) between 1 and 150  $\mu$ M and a Ki(glyphosate)/Km(PEP) ratio between about 2 and 500," or require "exhibiting tolerance to N-phoshonomethylglycine herbicide at a rate of 1 lb/acre without significant yield reduction due to herbicide application" while original claim 86 of the '435 Patent recites these limitations.

#### **Monsanto Response:**

CONTROVERTED that the challenged claims of the '247 Patent asserted by Monsanto are "promoterless." [See evidence cited in Response to Defendants' purported facts 11 and 13].

UNCONTROVERTED but IMMATERIAL and IRRELEVANT that those particular claims do not recite the specific enzymatic characteristics set forth in claim 86 of the '435 Patent, which is narrower than claim 4 of the '435 Patent.

# <u>Defendants' Purported Facts Nos. 15 – 21 Are Not Facts To Which A Response Is Required:</u>

Defendants' purported facts 15 through 21 – and each of the headings contained in Defendants' Statement of Facts – contain only mischaracterizations of Monsanto's pleadings and legal positions, and are not "facts" to which any response is necessary. Monsanto denies that it has "admitted" that the '247 Patent claims are broader than the broadest claim (claim 4) of the '435 Patent, and refers the Court to Section IV (pages 18-20) of its brief in Opposition to Defendants' motion for partial summary judgment. To the extent any response is required, each of Defendants' purported "facts" is addressed below.

## **Defendants' Purported Fact No. 15**:

In Monsanto's Reply Memorandum in Support of its Motion for Partial Summary Judgment of Infringement, Monsanto admits claims 116, 119, 122 and 125 are broader than the claims of the '435 Patent. Monsanto has stated that claims 116, 119,122 and 125 do not require the production of a functioning EPSPS protein of SEQ ID NO:70. (See Dkt. [131] at 9, 11 (stating "the claim language necessarily emphasizes the information encoded by the nucleotide sequence of the DNA – and not to the ultimate EPSPS protein as it functions within the plant cell"; stating such claim language "by its explicit terms, specifies only the DNA sequence – it does not require that the resulting expressed protein be the exact sequence of SEQ ID NO:70 . . ." (emphasis in original)). In contrast, claims 4, 15 and 32 of the '435 Patent each require that "the promoter is . . adapted to cause sufficient expression of the EPSPS enzyme to enhance . . . glyphosate tolerance." (See SOF, Ex. A, claims 4, 15 and 32).

## **Monsanto Response:**

Defendants' purported fact is a mischaracterization of Monsanto's statements and legal position. Monsanto has not admitted, and in fact denies, claims 116, 119, 122 and 125 are broader than the claims of the '435 Patent. Monsanto refers the Court to pages 18-20 of its brief in opposition to the present motion. Monsanto also incorporates as if set forth fully herein its Reponses to Defendants' purported facts nos. 11-14.

## **Defendants' Purported Fact No. 16**:

Monsanto also interprets reissue claims 116, 119, 122 and 125 to not require actual "transcription and translation" of an EPSPS enzyme having the sequence of SEQ ID NO:70. (Dkt. [131] at 11-12). Monsanto has stated that there is no "limitation to the claims" that requires a "functional glyphosate-tolerant enzyme of SEQ ID NO:70" to be produced at all. (Dkt. [131] at 11; *accord* Dkt. [131] at 22 ("the subject claims, when properly construed, look only to the presence of the EPSPS encoding *DNA sequence without regard to its ultimate expression product*" (emphasis in original)).

#### **Monsanto Response:**

Defendants' purported fact is a mischaracterization of Monsanto's statements and legal position. Monsanto has not admitted, and in fact denies, claims 116, 119, 122 and 125 are broader than the claims of the '435 Patent. Monsanto refers the Court to pages 18-20 of its brief

in opposition to the present motion. Monsanto also incorporates as if set forth fully herein its Reponses to Defendants' purported facts nos. 11-14.

## **Defendants' Purported Fact No. 17**:

Monsanto admits that the asserted claims do not specify a mechanism by which the plant is glyphosate tolerant, stating "[h]ere, the claim language [of the asserted claims] itself merely requires that the plants be glyphosate tolerant with no additional requirement as to the precise mechanism to achieve tolerance." (*See* Dkt. [131] at 8). Thus, Monsanto admits that these claims are broader than original claims 4, 15 and 32 which require that a "promoter is . . . adapted to cause sufficient expression of the EPSPS enzyme to enhance . . . glyphosate tolerance." (*See* SOF, Ex. A, claims 4, 15 and 32).

## **Monsanto Response:**

Defendants' purported fact is a mischaracterization of Monsanto's statements and legal position. Monsanto has not admitted, and in fact denies, that the asserted claims are broader than claim 4 of the '435 Patent. Monsanto refers the Court to pages 18-20 of its brief in opposition to the present motion. Monsanto also incorporates as if set forth fully herein its Reponses to Defendants' purported facts nos. 11-14.

## **Defendants' Purported Fact No. 18:**

Monsanto further admits that the asserted claims do not require a recombinant, functional, heterologous, promoter or recombinant, functional 3' NTR stating "[b]ecause the claims at issue are directed to a DNA sequence, regulatory data relating to an RNA or protein sequence is not relevant." (Dkt. [125] at 11).

## **Monsanto Response:**

Defendants' purported fact is a mischaracterization of Monsanto's statements and legal position. Monsanto has not admitted, and in fact denies, that the asserted claims are broader than claim 4 of the '435 Patent and do not require the functional elements stated above. Monsanto

refers the Court to pages 18-20 of its brief in opposition to the present motion. Monsanto also incorporates as if set forth fully herein its Reponses to Defendants' purported facts nos. 11-14.

## **Defendants' Purported Fact No. 19**:

Further, Monsanto has maintained that the asserted claims need not be glyphosate tolerant due to expression of an EPSPS enzyme, asserting that the claims cover the "ability to make plants 'glyphosate tolerant' without any reference to whether that tolerance arises by virtue of the EPSPS gene, the GOX gene, or the combined effect of both." (Dkt. [131] at 9).

## **Monsanto Response:**

Defendants' purported fact is a mischaracterization of Monsanto's statements and legal position. Monsanto has not admitted, and in fact denies, that the asserted claims do not require functional DNA that confers the claimed glyphosate tolerance in plant cells, plants, and seeds. Monsanto refers the Court to pages 18-20 of its brief in opposition to the present motion. Monsanto also incorporates as if set forth fully herein its Reponses to Defendants' purported facts nos. 11-14.

#### **Defendants' Purported Fact No. 20**:

Monsanto admits that "nothing in the plain claim language [of the asserted claims of 116, 119, 122 and 125] specifies any such parameters for glyphosate tolerance." (Dkt. [131] at 8). Monsanto, therefore, admits that these claims are broader than original claim 86 of the '435 Patent, which requires a plant to "exhibit[] tolerance to Nphoshonomethylglycine herbicide at a rate of 1 lb/acre without significant yield reduction due to herbicide application." (*See* SOF, Ex. A, at claim 86).

# Monsanto Response:

Defendants' purported fact is a mischaracterization of Monsanto's statements and legal position. Monsanto has not admitted, and in fact denies, that claims 116, 119, 122, and 125 of the '247 Patent are broader than the broadest claim (claim 4) of the '435 Patent. Monsanto refers the Court to pages 18-20 of its brief in opposition to the present motion. Monsanto also incorporates as if set forth fully herein its Reponses to Defendants' purported facts nos. 11-14. It

is irrelevant as a matter of law whether those claims are broader than all claims (including claim 86) of the '435 Patent.

## **Defendants' Purported Fact No. 21**:

Throughout Monsanto's briefing of its motion for partial summary judgment of infringement, Monsanto never asserts that the claims 116, 119, 122 or 125 require a recombinant, functional, heterologous promoter, or recombinant, functional 3' NTR, conceding that these are not elements of those claims. (*See* Dkts. [98, Attachment 1] at ¶¶ 21-25; [98] and [131] (focusing exclusively on whether a DNA sequence corresponds to an EPSPS enzyme having the sequence of SEQ ID NO: 70 of the '247 Reissue Patent, and omitting any discussion of the presence of a recombinant, functional, heterologous promoter, or recombinant, functional 3' NTR)).

## **Monsanto Response:**

Defendants' purported fact is a mischaracterization of Monsanto's statements and legal position. Monsanto has not "conceded" that the elements described above are not elements of those claims. Monsanto refers the Court to pages 18-20 of its brief in opposition to the present motion. Monsanto also incorporates as if set forth fully herein its Reponses to Defendants' purported facts nos. 11-14.

## MONSANTO'S ADDITIONAL MATERIAL FACTS

- 1. The asserted claims, 115-119 and 122-125, all require a "glyphosate tolerant plant" or a "glyphosate tolerant plant cell" that comprises a DNA construct encoding an EPSPS enzyme having SEQ ID NO:70 (an amino acid sequence listed in the '247 patent's specification). Ex. 1,'247 Patent
- 2. It would be scientifically impossible for a plant or plant cell to be glyphosate tolerant due to DNA encoding SEQ ID NO:70 (or due to a specific protein with SEQ ID NO:70, according to Defendants' claim construction), unless the structural gene was associated with specific elements for a gene to function in a plant or plant cell, including a heterologous promoter and 3' non-translated region. (Dellaporta Decl., ¶ 7)

- 3. A promoter is an essential functional element in a gene. (Dellaporta Decl., ¶¶ 8-19); see also **Defendants' expert** Jacobson's Declaration in Support of Defendants' Opening Claim Construction Brief, [Dkt 257] ¶¶ 59-60 (promoter and 3' NTR required "for a DNA coding region or structural sequence to function in a plant cell")
- 4. Without a promoter, a structural DNA sequence would be incapable of being transcribed. (Dellaporta Decl., ¶¶ 8-19); *see also Defendants' expert* Jacobson's Declaration in Support of Defendants' Opening Claim Construction Brief, ¶¶ 59-60 (promoter and 3' NTR required "for a DNA coding region or structural sequence to function in a plant cell")
- 5. In order to function in plant cells, the promoter must be heterologous with respect to the structural DNA sequence. (Dellaporta Decl., ¶ 15); *see also Defendants' expert*Jacobson's Declaration in Support of Defendants' Opening Claim Construction Brief, [Dkt 257]

  ¶ 74 ("When used to drive expression of an EPSPS gene, a plant virus promoter is considered "heterologous" with respect to the EPSPS structural DNA sequence, because the promoter and EPSPS structural DNA originate from different species.")
- 6. In order to function in plant cells, the promoter cannot come from the same gene as the structural DNA sequence. (Dellaporta Decl., ¶ 15)
- 7. A homologous promoter from the CP4 EPSPS gene will not work to confer glyphosate tolerance in plant cells. (Dellaporta Decl., ¶ 18)
- 8. Claims 115-119 and 122-125 necessarily require a functional, heterologous Promoter. (Dellaporta Decl., ¶¶ 12-19)

- 9. There is no possible plant that is glyphosate tolerant due to structural DNA encoding an EPSPS enzyme containing SEQ ID NO:70, but which lacks a heterologous promoter. (Dellaporta Decl., ¶ 19)
- 10. The 3' non-translated region (3' NTR) is an essential element of a gene required for it to work in a plant cell. (Dellaporta Decl., ¶¶ 8-11, 20-24); *see also Defendants' expert*Jacobson's Declaration in Support of Defendants' Opening Claim Construction Brief, [Dkt 257]

  ¶¶ 59-60 (promoter and 3' NTR required "for a DNA coding region or structural sequence to function in a plant cell").
- 11. Claims 115-119 and 122-125 necessarily require a functional 3' NTR. (Dellaporta Decl., ¶¶ 8-11, 20-24)
- 12. There is no possible plant that is glyphosate tolerant due to structural DNA encoding an EPSPS enzyme containing SEQ ID NO:70, which lacks a 3' non-translated region. (Dellaporta Decl., ¶¶ 23-24)
- 13. DNA encoding SEQ ID NO:70, as stated in claims 115-119 of the '247 patent, falls within the genus of compounds claimed in Claim 4 of the '435 patent. (Dellaporta Decl., ¶ 25).
  - a. The specific motifs defined in Claim 4 of the '435 patent are:

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Motif -R-X<sub>1</sub>-H-X<sub>2</sub>.E--G-D-K-X<sub>3</sub>--S-A-Q-X<sub>4</sub>-K--N-X<sub>5</sub>-T-R- whereby, X<sub>1</sub> is G, S, T, C, Y, N, Q, D or E; X<sub>2</sub> is S or T; X<sub>3</sub> is S or T; X<sub>4</sub> is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y or V; and X<sub>5</sub> is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y or V. (Dellaporta Decl., \P 26; Ex. 10, '435 Patent at 159:21-48)
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b. The sequence present in SEQ ID NO: 70 that matches the motifs in Claim 4 of the '435 patent are:

SeqID 70 Match
-R-D-H-T-E at position 200...204
-G-D-K-S- at position 26...29
-S-A-Q-V-K- at position 173...177
-N-P-T-R- at position 271...274

(Dellaporta Decl., ¶ 26); Ex. 1, RE '247 Patent at 153-56

- 14. During the prosecution of the reissue, the patent examiner specifically reviewed, amended and approved the challenged reissue claims. (Ex. 2, July 18, 2003, Second Preliminary Amendment and Remarks at 8; Ex. 3, Interview Summary at 1; Ex. 11, July 6, 2005 Response to Office Action at 32).
- 15. Claim 120 of the reissue application (the claim that eventually issued as claim 116), originally read as follows:
  - 120 (NEW) A plant comprising an EPSPS enzyme having the sequence of SEQ ID NO: 70.
  - (Ex. 2, July 18, 2003, Second Preliminary Amendment and Remarks at 8)
- 16. During an in-person interview in July 2004, the examiner agreed that the new SEQ ID NO:70 claims were fully supported by the specification (Ex. 3, Interview Summary at 1; Ex. 11, July 6, 2005 Response to Office Action at 32).
- 17. After an in-person interview on June 2, 2005, the *Examiner* himself, in September 2005, entered an amendment changing the language of claim 120 of the reissue application to require:
  - 120 A *glyphosate-tolerant plant* comprising *a DNA sequence encoding* an EPSPS enzyme having the sequence of SEQ ID NO:70.

(Ex. 4, Examiner-Initiated Interview Summary; Ex. 5, Sept. 12, 2005, Examiner's Amend. at 5).

Dated: July 12, 2010

Respectfully submitted,

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## **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on the 12th day of July, 2010, the foregoing was filed electronically with the Clerk of the Court for the United States District Court Eastern District of Missouri, Eastern Division, and was served by operation of that Court's electronic filing system, upon the following:

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